RECEIVED
CENTRAL FAX CENTER
AUG 3 - 2006

Remarks

The Office Action mailed 5 April 2006 has been received and reviewed. Claims 1, 4, 14-15, and 18-19 having been amended, claims 2-3 and 16-17 having been canceled herein, and claims 20-34 having been added, the pending claims are claims 1, 4-15, and 18-34.

Claim 1 has been amended, and new claims 20, 23, 28, and 32 added, to recite "a propellent," which is supported, for example, by dependent claim 2 (now canceled).

Claims 1 and 4 have been amended, and new claims 21, 24, 29, and 33 added, to recite "the proviso that the propellant is not air." The negative limitation that the propellant is not air is supported by the positive recitation of the alternative of the propellant being air in the specification at, for example, page 9, lines 27-28, which recites "a propellant (e.g., air, nitrogen, carbon dioxide, and hydrocarbons)." *See, for example*, M.P.E.P. §2173.05(i), which states that "[i]f alternative elements are positively recited in the specification, they may be explicitly excluded in the claims."

Claims 14 and 18 have been amended to delete the term "acid neutralizers," and claims 15 and 19 have been amended to delete the term "sodium bicarbonate." Claims 18 and 19 have been further amended by deleting the term "propellant" and reintroducing the term in new dependent claims 20 and 23.

New claims 22, 25, and 34 recite that the composition is in the form of a fine mist, which is supported, for example, by originally filed claim 3 (now canceled).

New independent claims 26 and 30 are generally supported by claims 14 and 18. New independent claims 26 and 30 further recite "an effective amount of an acid neutralizer active agent," which is supported by the specification in general, and specifically at, for example, page 8, line 29 to page 9, line 18. New dependent claims 27 and 31 are supported by the specification at, for example, page 9, lines 1-2.

Reconsideration and withdrawal of the rejections are respectfully requested.

Rejection under 35 U.S.C. §102

The Examiner rejected claims 1-3 and 4-17 under 35 U.S.C. §102(b) as being anticipated by Vacanti (U.S. Patent No. 5,944,754). Claims 1, 4, and 14-17 having been amended and claims 2-3 having been canceled, this rejection is respectfully traversed.

Independent claims 1 and 4 (as amended) each recite a propellant, with the proviso that the propellant is not air. As noted by the Examiner, Vacanti recites a spraying device that can be "employed in surgery to spray air or water over a desired surface" (column 8, lines 39-40). However, Vacant lacks, among other things, a disclosure of a propellant that is not air. For at least this reason, Applicants respectfully submit that independent claims 1 and 4, and dependent claims 5-13 are not anticipated by Vacanti.

With respect to independent claim 14 (as amended), Applicants respectfully submit that Vacanti fails to disclose, among other things, a spray device including an adjuvant selected from the group consisting of acids, peroxides, fluoride sources, medicaments, stability promotors, preservatives, adhesive modifiers, fillers, dyes, flavorings, sweeteners, and breath freshners.

However, the Examiner pointed to the recitation of "low molecular weight saccharides" in Vacanti (i.e., column 6, lines 11-12) and alleged that "[t]he 'low molecular weight saccharides' and salts . . . promote the 'stability' of the gels and increase their adhesiveness, and thus are 'stability promoters', as well as 'adhesive modifiers' " (page 5 of the Office Action mailed 5 April 2006). Applicants respectfully disagree.

In discussing temperature-dependent hydrogels, Vacanti recites that

> [t]hese copolymers can be manipulated by standard techniques to affect their physical properties such as porosity, rate of degradation, transition temperature, and degree of rigidity. For example, the addition of low molecular weight saccharides in the presence and absence of salts affects the lower critical solution temperature (LCST) of typical thermosensitive polymers. (Column 6, lines 8-14).

Thus, it is clear that Vacanti recites low molecular weight saccharides as affecting the lower critical solution temperature (LCST) of typical thermosensitive polymers. However, there is no disclosure or suggestion by Vacanti of the Examiner's totally unsupported assertion that such low molecular weight saccharides promote the "stability" of the gels and increase their adhesiveness, and thus are "stability promoters" and "adhesive modifiers."

Applicants respectfully submit that the Examiner's unsupported assertions are insufficient to support a *prima facie* case of anticipation of independent claim 14.

With respect to independent claim 15 (as amended), Applicants respectfully submit that Vacanti fails to disclose, among other things, a spray device including an adjuvant selected from the group consisting of anti-microbial agents, anti-calculus agents, anti-fungal agents, cariostatic agents, local anesthetics, glucose oxidases, and lactoperoxidases.

However, the Examiner pointed to the recitation of "low molecular weight saccharides" in Vacanti (i.e., column 6, lines 11-12) and alleged that "[t]hey would also be osmotic agents and thus would be reasonably expected to be (*sic*) function as 'anti-microbial agents' " (page 5 of the Office Action mailed 5 April 2006). Applicants respectfully disagree.

In discussing temperature-dependent hydrogels, Vacanti recites that

> [t]hese copolymers can be manipulated by standard techniques to affect their physical properties such as porosity, rate of degradation, transition temperature, and degree of rigidity. For example, the addition of low molecular weight saccharides in the presence and absence of salts affects the lower critical solution temperature (LCST) of typical thermosensitive polymers. (Column 6, lines 8-14).

Thus, it is clear that Vacanti recites low molecular weight saccharides as affecting the lower critical solution temperature (LCST) of typical thermosensitive polymers. However, there is no disclosure or suggestion by Vacanti of the Examiner's totally unsupported assertion that such low

molecular weight saccharides are osmotic agents, and thus would function as "anti-microbial agents."

Further, to the extent that the Examiner is implying that low molecular weight saccharides are ***inherently*** osmotic agents, and the osmotic agents are ***inherently*** anti-microbial agents, Applicants earnestly disagree. Applicants respectfully submit that whether a low molecular weight saccharide would or would not be an osmotic agent could depend on a number of factors including, for example, the specific composition of the low molecular weight saccharide, the medium in which the low molecular weight saccharide is present, the temperature of the medium, and the concentration of the low molecular weight saccharide in the medium. Similarly, whether an osmotic agent would or would not be an anti-microbial agent could depend on a number of factors including, for example, the specific composition of the osmotic agent, the medium in which the osmotic agent is present, the temperature of the medium, and the concentration of the osmotic agent in the medium. Thus, Applicants respectfully submit that the Examiner failed to show that low molecular weight saccharides are inherently anti-microbial agents. Moreover, for at least the reason that Vacanti is directed to hydrogel-cell "compositions and methods for generating new tissue on a surface" (abstract), one of skill in the art would have no motivation to include antimicrobial agents in the hydrogel-cell compositions.

Applicants respectfully submit that the Examiner's unsupported assertions are insufficient to support a *prima facie* case of anticipation of independent claim 15.

For at least these reasons, Applicants respectfully request that the Examiner reconsider and withdraw the rejection of claims 1-3 and 4-15 under 35 U.S.C. §102 as being anticipated by Vacanti.

Rejection under 35 U.S.C. §103

The Examiner rejected claims 2, 4-13, 18, and 19 under 35 U.S.C. §103(a) as being unpatentable over Vacanti (U.S. Patent No. 5,944,754). Claims 1, 4, 18, and 19 having been amended, and claim 2 having been canceled, this rejection is respectfully traversed.

Claim 1 has been amended to incorporate the language of claim 2 (now canceled). However, to the extent that the rejection still applies to claim 1 (as amended), Applicants respectfully traverse the rejection.

Independent claims 1 and 4 (as amended) each recite a propellant, with the proviso that the propellant is not air. As noted by the Examiner, Vacanti recites a spraying device that can be "employed in surgery to spray air or water over a desired surface" (column 8, lines 39-40). However, Vacant lacks, among other things, a disclosure of a propellant that is not air.

Nonetheless, the Examiner asserted that "the use of a device as simple and widely available as an aerosol container containing a propellant would surely have been obvious" (page 6 of the Office Action mailed 5 April 2006). Applicants respectfully submit that the Examiner's argument is nothing more than an impermissible "obvious to try" allegation. *See, for example*, M.P.E.P. §2143.01(IV), reciting that "[a] statement that modifications of the prior art to meet the claimed invention would have been "'well within the ordinary skill of the art at the time the claimed invention was made'" because the references relied upon teach that all aspects of the claimed invention were individually known in the art is not sufficient to establish a *prima facie* case of obviousness without some objective reason to combine the teachings of the references" (emphasis in original). Thus, Applicants respectfully submit that the Examiner failed to provide motivation to modify Vacanti sufficient to support a *prima facie* case of obviousness.

Further, Applicants respectfully submit that if one of skill in the art were arguably motivated to modify Vacanti by including a propellant, the propellant would likely be air, because other potential propellants might be undesirable in the surgical setting due, for example, to flammability concerns (e.g., propane) and/or unknown or potential deleterious health effects (e.g., partially fluorinated hydrocarbons). Thus, Applicants respectfully submit that the Examiner failed to establish the motivation necessary for one of skill in the art to modify Vacanti by including a propellant that is not air.

For at least these reasons, Applicants respectfully submit that the Examiner failed to establish a *prima facie* case of obviousness of claims 1 and 4, and dependent claims 5-13 as being unpatentable over Vacanti.

With respect to independent claim 18 (as amended), Applicants respectfully submit that Vacanti fails to disclose or suggest, among other things, a dental composition including an adjuvant selected from the group consisting of acids, peroxides, fluoride sources, medicaments, stability promotors, preservatives, adhesive modifiers, fillers, dyes, flavorings, sweeteners, and breath fresheners.

However, the Examiner pointed to the recitation of "low molecular weight saccharides" in Vacanti (i.e., column 6, lines 11-12) and alleged that "[t]he 'low molecular weight saccharides' and salts . . . promote the 'stability' of the gels and increase their adhesiveness, and thus are 'stability promoters', as well as 'adhesive modifiers' " (page 5 of the Office Action mailed 5 April 2006). Applicants respectfully disagree for at least the reasons discussed herein above in response to the rejection of claim 14 under 35 U.S.C. §102.

Further, the Examiner noted that "working example 5 uses a composition comprising a reverse-thermosensitive hydrogel as used in working example 2, seeded with articular cartilage chondrocyte cells which were grown in 5% CO_2 in a media composed of Hamm's F12 and 10% fetal bovine serum" (paragraph bridging pages 5-6 of the Office Action mailed 5 April 2006). The Examiner then alleged that "[t]he media thus would inherently contain sodium bicarbonate and various enzymes and salts, while the chondrocyte cells present therein would also contain various acids, salts, enzymes, antimicrobial agents and sodium bicarbonate as well." (Paragraph bridging pages 5-6 of the Office Action mailed 5 April 2006). Applicants respectfully disagree with the Examiner's allegation.

Applicants respectfully submit that a careful reading of Vacanti's Example 5 reveals that chondrocyte cells were allowed to multiply in a media composed of Hamm's F12 and 10% fetal bovine serum, and that a reverse-thermosensitive copolymer hydrogel was seeded with

chondrocyte cells. However, there is no clear indication in Vacanti's Example 5 that the media in which the cells were allowed to multiply was present in the reverse-thermosensitive copolymer hydrogel. Thus, the Examiner's allegation that "[t]he media thus would inherently contain sodium bicarbonate and various enzymes and salts" is not necessarily relevant to the composition of the reverse-thermosensitive copolymer hydrogel disclosed in Vacanti's Example 5. Further, the Examiner provided no evidence to support his allegation that the chondrocyte cells contain acids, and if such acids were present in the chondrocyte cells, that such acids would remain as such upon addition of the chondrocyte cells to Vacantis' reverse-thermosensitive copolymer hydrogel.

Finally, Applicants respectfully submit that the Examiner failed to provide motivation sufficient to support a *prima facie* case of obviousness to modify Vacanti to include an adjuvant selected from the group consisting of acids, peroxides, fluoride sources, medicaments, stability promotors, preservatives, adhesive modifiers, fillers, dyes, flavorings, sweeteners, and breath fresheners.

With respect to independent claim 19 (as amended), Applicants respectfully submit that Vacanti fails to disclose or suggest, among other things, a spray device including an adjuvant selected from the group consisting of anti-microbial agents, anti-calculus agents, anti-fungal agents, cariostatic agents, local anesthetics, glucose oxidases, and lactoperoxidases.

However, the Examiner pointed to the recitation of "low molecular weight saccharides" in Vacanti (i.e., column 6, lines 11-12) and alleged that "[t]hey would also be osmotic agents and thus would be reasonably expected to be function (*sic*) as 'anti-microbial agents' " (page 5 of the Office Action mailed 5 April 2006). Applicants respectfully disagree for at least the reasons discussed herein above in response to the rejection of claim 15 under 35 U.S.C. §102.

Further, the Examiner noted that "working example 5 uses a composition comprising a reverse-thermosensitive hydrogel as used in working example 2, seeded with articular cartilage chondrocyte cells which were grown in 5% CO_2 in a media composed of Hamm's F12 and 10%

fetal bovine serum" (paragraph bridging pages 5-6 of the Office Action mailed 5 April 2006). The Examiner then alleged that "[t]he media thus would inherently contain sodium bicarbonate and various enzymes and salts, while the chondrocyte cells present therein would also contain various acids, salts, enzymes, antimicrobial agents and sodium bicarbonate as well." (Paragraph bridging pages 5-6 of the Office Action mailed 5 April 2006). Applicants respectfully disagree with the Examiner's allegation.

Applicants respectfully submit that a careful reading of Vacanti's Example 5 reveals that chondrocyte cells were allowed to multiply in a media composed of Hamm's F12 and 10% fetal bovine serum, and that a reverse-thermosensitive copolymer hydrogel was seeded with chondrocyte cells. However, there is no clear indication in Vacanti's Example 5 that the media in which the cells were allowed to multiply was present in the reverse-thermosensitive copolymer hydrogel. Thus, the Examiner's allegation that "[t]he media thus would inherently contain sodium bicarbonate and various enzymes and salts" is not necessarily relevant to the composition of the reverse-thermosensitive copolymer hydrogel disclosed in Vacanti's Example 5. Further, although the Examiner made the unsupported allegation that the chondrocye cells contain "various enzymes," the Examiner failed to provide evidence or to even allege that the chondrocyte cells contain glucose oxidases and/or lactoperoxidases. In addition, the Examiner provided no support for his allegation that chondrocyte cells contain "antimicrobial agents." Moreover, for at least the reason that Vacanti is directed to hydrogel-cell "compositions and methods for generating new tissue on a surface" (abstract), one of skill in the art would have no motivation to include antimicrobial agents in the hydrogel-cell compositions.

Finally, Applicants respectfully submit that the Examiner failed to provide motivation sufficient to support a *prima facie* case of obviousness to modify Vacanti to include an adjuvant selected from the group consisting of anti-microbial agents, anti-calculus agents, anti-fungal agents, cariostatic agents, local anesthetics, glucose oxidases, and lactoperoxidases.

In view of the amendments and remarks presented herein, reconsideration and withdrawal of the rejections under 35 U.S.C. §103 are respectfully requested.

New Claims

New claims 20-22 and 23-25 depend ultimately or directly from independent claims 18 and 19, respectively. Applicants respectfully submit that claims 20-22 and 23-25 are patentable for at least the reasons recited herein above for the patentability of claims 18 and 19, respectively.

New claims 26-29 recite a spray device including: a container; an aqueous dental composition in the container, the composition including: about 10% by weight to about 50% by weight of a thermally responsive viscosity modifier based on the total weight of the composition; an effective amount of an acid neutralizer active agent; and water; wherein the composition is in a low viscosity state at a pre-treatment temperature and a highly viscous state at a treatment temperature that is higher than the pre-treatment temperature; and a sprayer in fluid communication with the dental composition, the device being capable of spraying the dental composition as a fine mist into the oral environment.

New claims 30-34 recite a dental composition capable of being sprayed as a fine mist into the oral environment, the composition including: about 10% by weight to about 50% by weight of a thermally responsive viscosity modifier based on the total weight of the composition; water; and an effective amount of an acid neutralizer active agent, wherein the composition is in a low viscosity state at a pre-treatment temperature and a highly viscous state at a treatment temperature that is higher than the pre-treatment temperature.

Applicants respectfully submit that claims 26-34 are patentable over Vacanti for at least the reason that Vacanti fails to disclose or suggest a dental composition as described in claims 30-34, or a spray device including a dental composition as described in claims 26-29, wherein the composition includes an effective amount of an acid neutralizer active agent. Applicants note that the Examiner, in discussing Vacanti, alleged that "[t]he media thus would inherently contain sodium bicarbonate . . . while the chondrocyte cells present therein would also contain . . .sodium bicarbonate as well" (page 6 of the Office Action mailed 5 April 2006). The allegation has been traversed herein above in response to the rejection of claims 18 and 19 under 35 U.S.C. §103 as

being unpatentable over Vacanti. In addition, Applicant note that the normal range of plasma bicarbonate concentration is approximately 22-26 millimolar as shown, for example, in *Harrison's Principles of Internal Medicine*, 15th Ed., McGraw-Hill (2001), Figure 50-1, page 285. Thus, Applicants respectfully submit that the amounts of sodium bicarbonate that might arguably be present in Vacanti's hydrogels from the chondrocyte cells therein, would be insufficient to be considered by one of skill in the art to be an effective amount of an acid neutralizer active agent (e.g., an active agent to neutralize acids generated by bacteria in the oral environment).

Entry and consideration of new claims 20-34 are respectfully requested.

Summary

It is respectfully submitted that all the pending claims are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted
By
Mueting, Raasch & Gebhardt, P.A.
P.O. Box 581415
Minneapolis, MN 55458-1415
Phone: (612) 305-1220
Facsimile: (612) 305-1228
Customer Number 26813

August 3, 2006
Date

By: _____
Loren D. Albin
Reg. No. 37,763
Direct Dial (612) 305-1225

CERTIFICATE UNDER 37 CFR §1.8:
The undersigned hereby certifies that the Transmittal Letter and the paper(s), as described hereinabove, are being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to **Mail Stop RCE**, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 3rd day of August, 2006, at 3:49 p.m. (Central Time).

By: _____
Name: Rachel Glaser-Gabra